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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/663,109

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Youcef M. Rustum

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EXAMINER

SIMMONS, CHRIS E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

03/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/663,109	Applicant(s) RUSTUM ET AL.	
	Examiner CHRIS E. SIMMONS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7-11 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-11 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/21/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Unless maintained *infra*, all previous rejections are withdrawn.

Scope of Enablement Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7-11, and 14 were rejected under 35 USC 112, first paragraph because the specification, while being enabled for methods for reducing hair loss in patients receiving 100 mg/kg to 150 mg/kg cyclophosphamide and 0.75 mg/kg methylselenocysteine, wherein the latter is administered orally daily for 21 days with the first dose being given at 14 days before cyclophosphamide treatment, does not reasonably provide enablement for treatment regimes using therapeutic protocols outside those specific parameters. The specification does not enable any person skilled in the art to which it pertains to, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues that the skilled artisan would know that alopecia is a predictable side effect of cyclophosphamide administration. Applicant further submits a declaration

under 37 CFR § 1.132 as support showing alopecia is a side effect of cyclophosphamide treatment.

Applicant's arguments have been fully considered and have been found persuasive insofar as alopecia being a predictable side effect of cyclophosphamide administration. However, with regards to enablement for reducing alopecia outside specific parameters, Applicant's arguments have not been found persuasive because the ability of selenium to reduce alopecia associated with cyclophosphamide administration is known to be particularly unpredictable as outlined in the prior office action and *infra*.

Applicant further argues that the Seija reference describes a clinical trial in which patients receiving combination therapy of cisplatin and cyclophosphamide and therefore the reference does not evaluate reducing alopecia caused by cyclophosphamide by using selenium.

Applicant has noted that hair loss is a predictable side effect of cyclophosphamide. Accordingly, a subject being administered cyclophosphamide, as is the case in the Seija reference, would then predictably have the side effect, alopecia. The reference discloses that no influence on hair loss was noted. If selenium had an effect on cyclophosphamide-induced hair loss, then there would at least be some influence on hair loss; in accordance, the selenium influence in reducing alopecia is not enabled outside of certain parameters disclosed in the instant specification.

Applicant submitted declaration (item 4) and the Fakhri reference as support for the claim that undue experimentation would not be required for reducing alopecia

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caused by cyclophosphamide administration by administering selenium containing compounds.

The Fakhri reference however, is evaluating selenium containing compounds' protective plasma levels for irinotecan-induced toxicities. The Fakhri reference further concluded that no major protection was established.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 7-11, and 14 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained.

Applicant's explanation has not been found to be persuasive because as the claim is currently recited, it remains unclear whether the therapeutically effective dose is effective for reducing alopecia or effective for treating cancer.

No claims are allowed.

Conclusion

The following is pertinent art not relied upon for this office action:

- USP 5,262,149

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chris E Simmons/
Examiner, Art Unit 1612

**/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612**